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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/099,823	06/19/98	BILLING-MEDEL	P	0200-0023.20

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EXAMINER	
ENEWOLD, J	
ART UNIT	**PAPER NUMBER**
1655	9

DATE MAILED: 11/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/099,823	BILLING-MEDEL ET AL.	
	Examiner	Art Unit	
	Jeanine A Enewold	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *08 September 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 30, 33, 35 and 38-42, drawn to a method of detecting the presence of a target BS124, a purified polynucleotide, a recombinant expression system, a cell transfected with recombinant expression, a composition of matter comprising BS124 a test kit and a gene or fragment, classified in class 536 subclass 23.5, class 435 subclass 6, 320.1, 325.

II. Claims 17-19, 34, drawn to a BS124 polypeptide, classified in class 530, subclass 350.

III. Claims 20, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claims 31-32, drawn to a method for producing antibodies, classified in class 424, subclass 130.1.

V. Claim 21-29 and 36-37, 43-44, drawn to method of detecting antibody and polypeptide, an assay kit, a method for producing a polypeptide comprising at least one BS124 epitope, method for detecting BS124 antigen, method for detecting the presence of antibodies, classified in class 435, subclass 7.1, 69.1.

The inventions are distinct, each from the other because of the following reasons:

A. The inventions of Groups I, II, and III are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group III is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Groups I, II, and III can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays, the antibody of Group III can be used in immunoassay, and the polypeptide of Group II can be used to make fusion protein with an enzymatic function, Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, and III are patentably distinct from each other.

B. The inventions of Group I and IV, and I and V are patentably distinct because the nucleic acid of Group I is not used in methods for producing antibodies as in Group

IV and the method of Group IV does not rely on nucleic acid of Group I. Also, the nucleic acid of Group I is not used in methods for producing polypeptides as in Group V and the methods of Group V does not rely on the nucleic acid of Group I.

C. The inventions of Group II and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used in a materially different process than producing antibodies as in Group IV. For example, the polypeptide may be used to make a fusion protien with enzymatic properties. Further, the antibodies may be produced in a different method other than administering an isolated polypeptide to an individual to elicite an immune response, such as the affinity purification of a polypeptide.

D. The inventions of Group II and V are related product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide

of Group II can be used in a method other than detecting a specific antigen, such as producing a fusion protein with enzymatic properties.

E. The inventions of Group III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibodies of Group III can be made in a materially different method other than administering a polypeptide to an individual to elicit an immune response, such as culturing of cells in vitro.

F. The inventions Group III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case. The inventions of Group III and Group V are patentably distinct from one another because the antibody of Group III can be used in a materially different process than detecting an antigen in a sample by contacting with the antibody molecule, or in a method of detecting the presence of antibodies in a sample. For example, the antibody of Group III could be administered to a patient.

G. The inventions of Group IV and V are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group IV is for producing antibodies by administering to an individual in vivo an isolated immunogenic polypeptide. Alternatively, the method of V is for producing a polypeptide which comprises incubating host cells in vitro with an expression vector. Therefore the methods are distinct over one another.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

4. A telephone call was made to Cheryl Becker on November 9, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold
November 24, 1999

Lisa B. Arthur

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP ~~1800~~ 1600